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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,823	08/28/2002	Michel Revel	REVEL=16	1533

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EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 02/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,823	REVEL ET AL.	
	Examiner	Art Unit	
	Fozia M Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Office Action

1. Receipt of Applicants' amendment and arguments filed in Paper No.13 on 10 November 2003 is acknowledged. Claims 5-8 have been canceled, claims 9-12 have been amended and claims 14-15 have been added. Claims 1-4 had been previously cancelled. Thus claims 9-15 are pending and under consideration.

2. The following previous objections and rejections are withdrawn in light of Applicants amendment filed on 11/10/03:

(I) All of the rejections against cancelled claims 5-8 are withdrawn.

(II) The rejection of claims 9-13 made under 35 U.S.C. 112, first paragraph, for lacking written description for the inerleukin-6 receptor-interleukin-6 chimera (IL6RIL6), used in the claimed method is withdrawn.

(III) The rejection of claim 12 made under 35 U.S.C. 112, first paragraph for not enabling a method of treating multiple sclerosis, said method comprising administering an effective amount of ILR6IL6 chimera, is also withdrawn.

(III) The rejection of claims 9-13 made under 35 U.S.C. 112, second paragraph, is also withdrawn.

New Rejections:

Claim rejections-35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3a. Claims 9-11, 13-15 are rejected under 35 U.S.C. 112, first paragraph, while being enabling for a method of treating a demyelinating disease of the central nervous system (CNS) or peripheral nervous system (PNS), said method comprising administering an effective amount of interleukin-6 receptor/interleukin-6 chimera (IL6RIL6), does not reasonably provide enablement for a method of treating " all" possible neurological diseases or disordering by administering an effective amount of ILRTL6 chimera. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Instant claim 9 recites a method of treating "a neurological disease or disorder", while claim 10 limits said disease to Alzheimer's disease, Parkinson's disease, or amyotrophic lateral sclerosis (ALS), however, the in-vitro experiments in this application show that the IL6RIL6 chimera induces the expression of myelin basic protein (MBP) and proteolipid protein (PLP), (see Examples 1-8, on pages 12-21). The specification also discloses that IL6RIL6 chimera inhibits oligodendrocyte proliferation by 40 to 50% compared to controls, (see Example 2). Example 8 of the instant specification uses a murine model of chronic relapsing multiple sclerosis. The art recognizes that chronic CNS demyelination (loss of oligodendrocytes, the myelinating cells in the CNS), is the cause of a number of disease conditions such as Multiple Sclerosis, and that in demyelinated areas as compared to normal white matter, there is an increase in the number of proliferating oligodendrocytes, expressing myelin basic protein.

Therefore, while the instant specification is enabling for a method of treating diseases that result from demyelination by administering an effective amount of IL6RIL6 chimera, it is not enabled for the treatment of "all" possible neuro-degenerative diseases by administering said chimera. Instant specification discloses that IL6RIL6 chimera might promote remyelination and that this would have potential therapeutic effect on demyelinating diseases. However, it is well known in the art that all neurdegenrative diseases are not the result of demyelination. For Example, in Alzheimer's disease neurons in the cortex and hippocampus and other areas of the brain die, while in Parkinson's disease dopamine producing cells in the substantia nigra die off. Therefore, it is not predictable from the experiments in the instant specification that IL6RIL6 chimera of the instant invention would have any effect on neurodegenrative diseases that are not caused by demyelination. The criteria set forth in Ex parte Forman (230 USPQ 546 (Bd. Pat. App. & Int. 1986), and reiterated in In re Wands (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)), which include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims, is the basis for determining undue extermination. In the instant case, due to the complexity of the neurodegenrative diseases, and due to the fact that instant specification only discloses that the IL6RIL6 chimera might be effective against diseases caused by demyeliantion, undue experimentation would be required for

the skilled artisan to test whether IL6RIL6 chimera can be used treat "all" possible neurological diseases or disorders. Thus instant specification is only enabling for a method of treating a demylinating disease of the central nervous system (CNS) or peripheral nervous system (PNS), said method comprising administering an effective amount of interleukin-6 receptor/interleukin-6 chimera (IL6RIL6).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 9-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4a. Claims 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claims 9 and 10 are drawn to a method for treating a disease, however, the claims do not recite a result step.

4b. Claims 9, 10, 14 and 15 recite the acronym "IL6RIL6 ", however, this acronym makes the claims unclear. Reciting the full name of the chimera in the first independent claim would obviate this rejection.

Claims 11, 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, insofar as they depend on claim 9 for the limitations set forth directly above.

Claim rejections-35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5a. Claims 9-15 are rejected under 35 U.S.C § 102(b) as being anticipated by Revel et al (WO 99/02552, 01/21/1999).

Revel et al disclose a pharmaceutical composition comprising a chimera of glycosylated soluble interleukin-6 receptor and interleukin-6, (sIL-6R/IL-6), and a method of using said chimera in the preparation of a medicament for treating neurological diseases, (pages 7-8 and page 11, lines 21-28).

Thus, since the Revel et al reference discloses that the IL6RIL6 chimera can be used to treat neurological diseases, it meets all the limitations recited in instant claims 9-15 and therefore, anticipates instant claims 9-15 in the absence of any evidence to the contrary.

Conclusion:

6. No claim is allowed.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud
Patent Examiner
Art unit 1647
09 February 2004

Prema Mertz
PREMA MERTZ
PRIMARY EXAMINER